From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Summer 1996 Volume 3, Issue 3

From the Editor…

We're now reviewing the hundreds of public comments sent in response to the proposed final Mammography Quality Standards Act (MQSA) regulations published in the April 3, 1996, Federal Register. *Thanks for your thoughtful responses.*

We'll be taking all submitted comments into consideration as we write the final regulations. The comments will be addressed in the preamble to the final rule.

For your convenience, here are the addresses, fax numbers, and phone numbers where we can be reached if you have questions or suggestions about our program, or if you wish to request MQSA information.

Questions about certification and inspection issues should be directed to:

Mammography Quality Assurance Program
Phone 800-838-7715
Fax 410-290-6351

Comments about or suggestions for Mammography Matters *should be sent to:*

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850
Fax 301-594-3306

Radiologic Technologists, Interpreting Physicians, Medical Physicists: Prepare for October 1997

Facilities should be aware that October 1, 1997, is an important date with respect to the continuing education requirement for most mammography personnel, including radiologic technologists, interpreting physicians, and medical physicists. Certain requirements, applicable only to medical physicists, also will change on October 27, 1997. Another date — October 1, 1996— is also important to both radiologic technologists and interpreting physicians, as described in the previous issue of *Mammography Matters* (Spring 1996).

October 1, 1997: Continuing Education Deadline

All mammography facility personnel were to have begun meeting the continuing education requirement of an average of 5 CME/CEU per year on either October 1, 1994, or the date they first met their initial requirements, whichever is later. However, FDA established a 3-year "grace period" during which failure to maintain this average would not be cited as a noncompliance. The beginning of the grace period is defined as the later of October 1, 1994, or the date on which personnel first met their initial requirements.

Personnel training and continuing education requirements will change on October 1, 1996, October 1, 1997, and October 27, 1997.

The grace period has allowed personnel more flexibility in selecting continuing education courses that best meet their needs. During the grace period, inspectors have been checking on progress made toward

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What's Inside

From the Director . . .

I'd like to take this opportunity to tell you a little more about our MQSA inspectors, two of whom are featured in an article in this issue of **Mammography Matters.**

Our inspectors are dedicated professionals who, like you, are very serious about ensuring that quality standards are met. To date, FDA has certified roughly 220 inspectors. To become certified, our inspectors undergo up to 6 weeks of training and must pass written and practical examinations. Each inspector must now have a bachelor's degree, an associate of science degree, or certification in radiologic technology. Some have master's or doctoral degrees or are M.D.s. Once the basic requirements are met, our inspectors must participate in continuing education in radiological health sciences or mammography as well. Once a year, every inspector's performance is audited and certifications to perform MQSA inspections are evaluated by FDA staff.

Many of you have been pleasantly surprised that your inspection "went better than anticipated" and have sent us compliments about the inspectors who have visited your facilities. Your words of support have given my staff and me great encouragement!

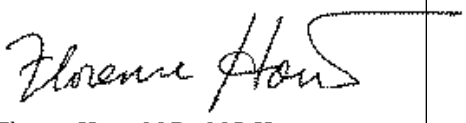
As mentioned in a previous column, however, we know we can do a better job. To this end, we have developed and implemented a variety of approaches to help improve inspector training and enhance communication among inspectors, accreditation bodies, FDA, and facilities.

For example, we have a mentoring program to ensure that new inspectors gain experience from seasoned inspectors. We have an inspection quality assurance program and hold annual teleconferences to educate our inspectors. We produce a newsletter targeted to inspectors and accreditation bodies that provides important inspection-related information. We also investigate and respond to any comments and complaints sent to us.

Inspections can be stressful, but we are doing our best to work with you in making your inspection run as smoothly as possible. And it seems that these efforts are really paying off.

Many of you have already had a second MQSA inspection. Using data from second-round inspections completed through May 1996, we found 66 percent fewer Level 1 findings (the most serious type of finding during an inspection) in the second round compared with the first round of inspections! Roughly 3 percent of 9,200 facilities had Level 1 findings in the first round, while only 1 percent of 1,108 facilities had similar findings in the second round. In addition, 50 percent of facilities inspected in the second round were without any findings, compared to 32 percent of facilities in the first round. This translates into an improvement of 56 percent! Finally, no facility with a Level 1 finding in its first year has repeated that same finding.

We are encouraged that so many of you, along with our inspectors, continue to make improving mammography quality a reality.



Florence Houn, M.D., M.P.H.,
Director, Division of Mammography
Quality and Radiation Programs

On the Trail of Two MQSA Inspectors

In the last issue of *Mammography Matters* (Spring 1996), we described the general role of the MQSA inspector. Now we'd like to introduce you to two MQSA inspectors—one FDA employee, one state employee—who have developed a unique working relationship that crosses state borders.

Robert (Bob) Antonsen, RT, B.S.

As a Consumer Safety Officer/Radiation Specialist in FDA's Denver office since 1994, Bob oversees radiation control contracts for several states within the agency's Southwest Region, including Colorado, Utah, Wyoming, and New Mexico. Approximately 15 years ago, he began his career in radiation technology after receiving degrees in radiation technology and radiation sciences from the Medical University of South Carolina in Charleston. Working initially as a registered radiologic technologist and later as a medical physicist, Bob logged in 10 years as a provider of comprehensive radiation and health physics support to hospitals, private physicians, industry, and research facilities.

In 1990, desiring a more active role in the application of radiation sciences to medicine, Bob joined the FDA's Center for Devices and Radiological Health (CDRH) as a health physicist. There he became involved in the center's Division of Mammography Quality and Radiation Programs (DMQRP), soon after its founding in 1993 to implement MQSA.

During his 4 years with CDRH, Bob continued to gain experience and broaden his expertise. He became involved in the cooperative federal-state Nationwide Evaluation of X-ray Trends (NEXT) surveys, serving as project officer for the 1993 dental study, and honed his skills in equipment calibration. Also, he helped develop MQSA policy and began teaching MQSA-based training courses.

Bob's current job provides many challenges, as he finds himself juggling the roles of MQSA inspector and auditor along with providing inspection services and technical assistance for x-ray system assembly and manufacturing operations. And as mentor to inspector-in-training Dewey Long, Bob has been able to share the many experiences and knowledge he has gained over the years.

Dewey Long, B.S., M.A.

Like Bob, Dewey has spent his career in the medical sciences, serving first as technologist in, and then as manager of, hospital-based clinical laboratories for more than

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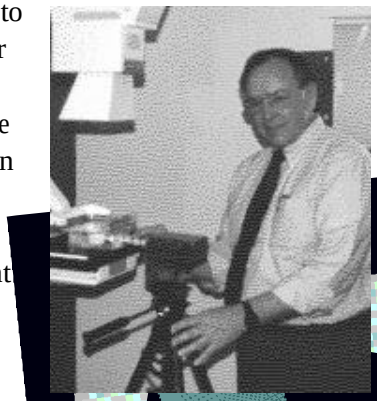

Dewey Long, B.S., M.A., is the Mammography and Laboratory S... of Health Quality in the Wyoming State Department of Health.

Robert Antonsen, RT, B.S., oversees radiation contracts for several states within the agency's Southwest Region, including Colorado, Utah, Wyoming, and New Mexico.

MQSA Inspectors

Continued from page 3

20 years. Over the past 11 years, Dewey has been the Mammography and Laboratory Survey Coordinator for the Office of Health Quality for the Wyoming State Department of Health. During this time, he trained with the Utah and Idaho radiological health programs and was responsible for inspecting about half of Wyoming's mammography facilities for the Health Care Financing Administration (HCFA).

Overcoming the Miles

The combination of Bob's base in Denver and Dewey's home front—the State of Wyoming—presented an interesting situation, according to Bob. About 2 years ago, Wyoming chose to write a contract to provide MQSA inspectors for state facilities. However, Wyoming has not had an active radiological health program since July 1990, leaving a significant gap in inspector training and facility inspections. In addition, Wyoming facilities needed to be inspected by the district FDA MQSA inspector until a state inspector was fully certified. Enter Bob Antonsen — mentor and inspector — and Dewey Long — inspector-in-training who became a certified MQSA inspector in January of this year.

Despite the miles that separated them, Dewey and Bob were able to establish a strong working relationship, taking advantage of each other's experience and contacts. Dewey proved to be a quick study, Bob points out. And Bob provided solid leadership as Dewey's mentor. Says Dewey, "I always feel assured that I have Bob Antonsen as a backup . . . he is a true rad health professional."

Inspectors Facilitate MQSA

Dewey sees the MQSA program—including his own inspector training and certification—as critical to improving mammography quality. "I think [the MQSA inspection program] is an assurance to facilities that their physicist is doing a good job, and that they have reliable equipment. The program assures that the mammography [services] they provide to their community are safe and effective and give the absolute best chance of early breast cancer detection," he says. "I feel good about being a part of that," he adds.

Bob agrees, noting that facilities in Wyoming have truly embraced the inspection process. Initially, facilities were concerned that "MQSA was going to force them out of business," he says, "but once they found out what the MQSA inspection entailed, they were put at ease. All of them have been very prepared [for the inspections] and are doing their best to assure high quality mammography services."

The MQSA program appears to be having a positive impact not only in Wyoming but throughout the Southwest Region and the nation, according to both inspectors. Bob says, "Based on records I've looked at, I can see that many [of the facilities] never even had a quality assurance [QA] program to speak of. However, most of them realized that if they had a decent QA program and followed QC [quality control] manuals put out by the ACR, then everything would fall into place."

Communication between inspectors and appropriate facility personnel is essential to the success of the inspection process. This improves understanding of the MQSA inspection process and helps facilities view inspectors and inspections as positives rather than negatives. And those lines of communication, Bob and Dewey agree, help the facilities they visit to do a quality job and enhance their own job satisfaction.

Commercial Marketing of Digital Mammography Equipment...

Most readers of *Mammography Matters* probably have heard about a new mammographic technology called digital mammography becoming available in the future. Because digital mammography is still considered to be in the research stage (it's being tested in clinical trials) and is not commercially available, it is exempted from meeting MQSA requirements. However, requirements of the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act do apply to digital mammography devices and must be met before the devices can be introduced into commerce.

The Office of Device Evaluation of FDA's Center for Devices and Radiological Health has published guidance for *manufacturers* of digital mammography equipment to aid them in meeting these requirements. Interested parties can obtain copies of this guidance from:

- Office of Device Evaluation
  Center for Devices and
  Radiologic Health (HFZ-470)
  9200 Corporate Blvd.
  Rockville, MD 20850
  301-594-5072, or
- Facts on Demand (if you have a fax machine and a touch-tone phone, dial 800-899-0381 or 301-827-0111 and follow the prompts), or
- FDA's home page on the World Wide Web (complete address: http://www.fda.gov/cdrh/blbkmem.html). The document will be made available on this page within a few weeks.

Those who plan to conduct clinical studies on digital mammography equipment should first contact the Office of Device Evaluation at the Rockville address and/or phone number listed above.

Part-Time and Temporary Personnel Must Meet MQSA Requirements

Both the MQSA and the interim regulations are clear that all interpreting physicians, radiologic technologists, and medical physicists who provide mammography services must meet the MQSA personnel qualifications, even if they provide these services only occasionally or on a temporary basis. This was our policy on October 1, 1994, and is still our policy.

However, during the initial period of adjustment to the new regulations, FDA exercised its inspection discretion by asking inspectors to focus on the qualifications of those individuals employed by, or providing mammography services to, the facility at the time of the inspection. The inspector was instructed to not routinely attempt to identify all individuals who had provided services in the past but were not currently doing so.

Now that we're well into the second round of inspections, facilities should be familiar with the MQSA requirements, and FDA believes that the effectiveness of its inspections will be enhanced by broadening this inspection policy.

Beginning January 1, 1997, inspectors will examine the qualifications of **all** *individuals providing mammography services to the facility since the date of the last inspection or since the date the facility received provisional certification, whichever date is later.* We are giving several months advance notice regarding this change to give facilities time to make necessary adjustments in their personnel record retention policy. We would like to emphasize again that *this is not a change in the MQSA requirements but rather a change in our inspection policy.*

Recap: 90-Day Extension Policy

FDA's one-time 90-day extension policy continues to be a source of confusion for some facilities. Also, some fully accredited facilities have applied for a 90-day extension when they should have applied to their accreditation body for reaccreditation.

Only facilities that have not yet been fully accredited and do not have a 3-year MQSA certificate may apply for a 90-day extension.

Perhaps most important, each provisionally accredited facility should be actively pursuing accreditation with its accreditation body to the best of its ability. FDA will contact the accreditation body to confirm that facilities without a 3-year certification are cooperating.

> Only provisionally accredited and provisionally reinstated facilities are eligible for a 90-day extension of their certificate.

Important information about applying for a 90-day extension policy includes:

1. Only provisionally accredited and provisionally reinstated facilities are eligible for a 90-day extension of their certificate.

2. Facilities accredited by the American College of Radiology (ACR) should apply to FDA at the following address for an extension:

   FDA MQSA
   P.O. Box 6057
   Columbia, MD
   21045-6057
   Fax 410-290-6351

   Receipt of your application may be confirmed by calling 800-838-7715.

3. Facilities accredited by Arkansas, California, or Iowa should apply directly to their state accreditation body.

4. The application letter should include the following information:
   - Request for extension
   - Description of circumstances that make the extension necessary
   - A specific description of the hardships the community will face if the facility cannot practice mammography
   - A contact person and phone number (a fax number is also helpful).

5. Processing applications for extensions can take up to 5 working days, so early application is appreciated.

6. IF YOUR FACILITY'S CERTIFICATE EXPIRES, YOU MUST STOP PRACTICING MAMMOGRAPHY IMMEDIATELY and contact your accreditation body for information regarding your facility's status.

Preparing For October 1, 1997

Continued from page 1

meeting the continuing education requirements, but only to identify problems while there still is time to correct them.

For facility personnel who met their initial requirements before October 1, 1994, the CME/CEU grace period will end on October 1, 1997. By that date, these personnel must have earned at least 15 CME/CEU in mammography since October 1, 1994, or they will not be in compliance with MQSA requirements.

October 27, 1997: Medical Physicist Initial Qualification Deadline

MQSA established several ways by which medical physicists can demonstrate that they are initially qualified to provide physics services to mammography facilities, including meeting FDA-defined training and experience qualifications.

As with the experience alternative for technologists (see *Mammography Matters*, Spring 1996), the experience alternative for medical physicists is not a permanent "grandparenting," but is being permitted for a limited time period. For medical physicists, this period is for 5 years after MQSA became law. Because MQSA was enacted on October 27, 1992, the 5 years will end on October 27, 1997. By that date, physicists who have been using the training and experience route must be:

- Certified in an FDA-approved specialty by an FDA-approved board, or
- State licensed or state approved.

Physicists who fail to meet these requirements by the specified date must stop providing physics services to mammography facilities.

Because the October 27, 1997, deadline was established by Congress in the law itself, FDA has no authority to modify it.

Note

The personnel requirements explained above, along with the effective dates, are in addition to the initial experience/training date requirement in the technologist qualifications and the continuing experience date requirement in the interpreting physician qualifications (see *Mammography Matters*, Spring 1996).

Important Upcoming October Dates for Facility Personnel

October 1, 1996

- For technologists, experience will no longer be acceptable as a substitute for mammography training.
- For most interpreting physicians, this is the date by which they must meet the continuing experience requirement. The exceptions are physicians who met their initial qualifications after October 1, 1994.

See the Spring 1996 issue of *Mammography Matters* for details of technologist initial experience/training and interpreting physician continuing experience requirements.

October 1, 1997

This is the date on which most mammography personnel must have earned at least 15 CME/CEU in mammography. Again, the exceptions are those personnel who met their initial qualifications after October 1, 1994. (See accompanying article in this issue of *Mammography Matters*, pages 1 and 7.)

October 27, 1997

By this date, medical physicists who have been using the training and experience route to meet MQSA qualifications must be:

- Certified in an FDA-approved specialty by an FDA-approved board, or
- State licensed or state approved.

Technical Corner by Orhan Suleiman, Ph.D.

The Technical Corner in Mammography Matters *provides facility personnel with helpful hints on various technical and equipment issues involved in meeting MQSA requirements. This section of the newsletter responds to inquiries that require too long an answer to be included in the Q & A section.*

More About Film Processors

This article is a followup to the Technical Corner article on MQSA inspection requirements for evaluating film processors (see the Spring 1996 issue of *Mammography Matters*). That article described the procedures an MQSA inspector uses to evaluate film processors. This article describes ways to make sure your processing adheres to the film manufacturer's specifications. It also explains how facility personnel can empirically verify that their processing results in "equivalent" film performance.

Film Processor Checks

The following steps may be taken to ensure that your film processor meets MQSA requirements:

Orhan H. Suleiman, Ph.D., Chief, Radiation Programs Branch, Division of Mammography Quality & Radiation Programs

1. Determine that the developer temperature, development time, and replenishment rates are consistent with manufacturer's specifications. (Problems here may be nothing more complex than an incorrectly set, inaccurate, or defective thermostat.)

2. Check the quality of the chemical processing solutions, which may have been improperly mixed by the factory, the local distributor, or the facility. If improper mixing occurs infrequently, your facility's quality control checks should detect the problem. *If improper mixing is common, and you question the quality of the chemical solution, you should obtain a batch of fresh chemicals directly from the manufacturer and mix the chemicals yourself.*

Processing Validation

After you've made any necessary corrections, you still need to confirm that your processing has "equivalent performance" to a properly operating processor. This can be done as follows:

1. Identify a processor that is known to be operating according to the film manufacturer's specifications. Ask your technical representative or your MQSA inspector to help identify a facility with a properly calibrated film processor.

2. For comparison tests, use the same sensitometer and densitometer for all your tests. Although there is no national standard for light sensitometry, any 21-step commercially available sensitometer is adequate, as long as you repeat the test using the same sensitometer.

3. Use the same type of mammography film for the comparison tests that you use in the clinical setting. The film should come from the same box and emulsion batch.

Technical Corner *(continued)*

4. Expose the control film to the designated standard sensitometer and develop it in a processor known to be operating properly. Then read the film with your densitometer.

5. Repeat step 4 in the processor you wish to evaluate. You now have two films: a standard reference film and a film for the test processor.

6. Calculate the processing speed by determining speed density. Speed density is the density equal to the base-plus-fog density (B + F) plus 1.0. A sensitometric step number (speed step) corresponding to the speed density is interpolated from the sensitometric curve of the film.

Processing speed is calculated from the following formula:

$$\text{Processing Speed} = 100 \times 10^{(S_r - S_o) \times 0.15}$$

Where:

Speed Density = 1.0 + (B + F)

S = Speed step, the sensitometric step number corresponding to the speed density

S_o = Observed speed for the tested processor

S_r = Reference speed step when the film is processed according to the film manufacturer's recommendations.

If S_o and S_r are equal, you can use a processing speed of 100 for standard processing (i.e., when a nominal 20-second development time is employed) or a processing speed between 130 and 140 for extended cycle processing speed (i.e., when a nominal 40-second development time is used).

As mentioned in the Technical Corner of the previous issue of *Mammography Matters*, the Sensitometric Evaluation of Processing (STEP) test is used during MQSA inspections to determine processor compliance. STEP action limits are based on a 20-percent difference in processing speed and correspond to a nominal 2.2-degree Celsius (4.0-degree Fahrenheit) developer temperature difference.

For additional information, refer to "Automatic Film Processing: Analysis of 9 Years of Observations," by O. H. Suleiman et al. (*Radiology* 185:25-28, 1992).

Help Line for Veterans Administration Mammography Facilities

The mammography office of the Veterans Administration (VA) has a new toll-free phone line that VA patients may use to learn the location of their nearest mammography facility and to inquire about mammography.

The toll-free VA mammography number is 888-492-7844. The number is staffed Monday through Friday, 8:00 a.m. to 4:30 p.m. Eastern Time.

Q & A

Q & A is a regular column in **Mammography Matters.** *We welcome your questions and will publish answers to any that are of general interest. Send your questions to* **Mammography Matters,** *FDA/CDRH (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, Fax 301-594-3306.*

Q An article in the last issue of *Mammography Matters* listed five ways for technologists to show satisfactory training in mammography, one of which is to have the advanced certificate in mammography from the American Registry of Radiologic Technologists (ARRT). Does this mean that if I meet one of the other criteria, I don't have to be ARRT certified?

A The answer depends on your state licensure laws. If you meet one of the other criteria, you needn't have the ARRT(M) to show the MQSA inspector adequate training in mammography. Don't forget, though, that technologists must also meet the requirement to have either a general technologist license from a state or the general ARRT certificate. So, depending on your state, you may need to have the ARRT(R) even though you don't need the ARRT(M) to meet the MQSA training requirement.

Incidentally, after we published the last issue of *Mammography Matters*, FDA accepted a sixth way for technologists to show adequate training—by earning the mammography certificate issued by Nevada. As before, if a technologist's training doesn't meet any of the six criteria, his or her background will be reviewed on a case-by-case basis.

Q I have another question about ARRT certification. As you mentioned, current possession of the ARRT(M) itself meets the technologist training requirement, but I've heard that if the final regulations proposed by FDA are adopted, the ARRT(M) will have no weight at all in meeting the technologist training requirements. Is this really true?

A No. Because the general statement in the interim regulations on technologist training led to many questions about the amount and content of the needed training, the proposed new regulations, developed with the advice of the National Mammography Quality Assurance Advisory Committee, are more specific. They also would require that the training include the performance of mammography exams under direct supervision.

Because the ARRT(M) can be earned without experience in performing mammography, having the ARRT(M) would not, by itself, mean a technologist has met *all* the training requirements of the proposed regulations. However, because the ARRT has rated the ARRT(M) as equivalent to receiving 24 CEU, earning this special certificate would still meet a significant portion of the proposed training requirements.

Q How long should I keep personnel records for our technologists, physicists, and interpreting physicians? What about records for temps, backups, and locum tenens?

A Beginning January 1, 1997, the inspector will ask to see qualifications for *all* personnel who've provided mammography services since the date of your last inspection or since you received your provisional certificate, whichever date is later. If someone leaves permanently, keep his or her records until you've had your next inspection.

Q & A *(continued)*

Q Is an x-ray unit that is moved to various rooms within a building considered a "mobile unit"? How is a mobile x-ray unit defined?

A No. X-ray units that are located on wheels and moved from room to room within a building are not considered "mobile." An x-ray unit is considered "mobile" if it is located in a van or truck for the purpose of providing mammography service to various locations.

Q Which facility is responsible for the correction of noncompliances identified during an MQSA inspection when the mammography examination, film processing, or interpretation of the mammogram occurs at more than one facility?

A The responsibility for the correction of noncompliances identified during an MQSA inspection rests with the facility that performs the mammogram. The Mammography Quality Standards Act states, "Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards ...." Thus, when mammography activities are split between facilities, the facility performing the mammogram will be notified and held responsible for problems. It will be up to the facility that performs the mammogram to (1) ensure that the remote or partial provider takes steps to correct noncompliances (or assure correction of noncompliances), or (2) terminate its connection with the partial provider if the partial provider does not meet MQSA standards.

Accreditation, Certification, and Commercial Products

FDA neither endorses nor requires the use of any specific x-ray system component, measuring device, software package, or other commercial product as a condition for accreditation or certification under MQSA.

Any representations, either orally or in sales literature, or in any other form, that purchase of a particular product is required in order to be accredited or certified under MQSA should be reported to FDA immediately so that appropriate action may be taken.

The mention or illustration of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by FDA.

Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested organizations and individuals.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

Fax 301-594-3306.

Florence Houn, M.D., M.P.H., Director, DMQRP, CDRH

Carole Sierka, Managing Editor; Chief, Outreach Staff, DMQRP, CDRH

Mickie Kivel, Editor, DMQRP, CDRH

Other contributors: Cathy Akey, Kathleen Baer, Roger Burkhart, Patricia Hoage, Orhan Suleiman, Jean Toth-Allen.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration (HFZ-240)
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

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